AUG 1 4 2002

K022242

510(K) SUMMARY

Trade Name: **InterVascular InterGard Knitted Vascular Graft Sizer**
Common Name: **Vascular Graft Sizer**

The InterVascular Graft Sizer, an accessory to the InterGard Knitted Vascular Prosthesis, consists of a set of 5 disposable dual gauge sizers and 1 disposable single gauge sizer constructed of a biocompatible material. The size indicated on the instrument approximately corresponds to the size of the lumen of the host vessel. The labeled sizes of the instrument are 6, 7, 8, 10, 12, 14, 16, 18, 20, 22, and 24mm. The surgeon makes the ultimate decision on the size of the graft.

The InterVascular Graft Sizer is designed to assist the physician in determining the size of the lumen of the host vessel in order to select the appropriate knitted vascular graft diameter.

Biocompatibility tests performed on the finished products show that the device is non-hemolytic and non-cytotoxic. In addition, extensive biocompatibility testing conducted on the material demonstrated its suitability for medical use in devices. The material tested for biological performance meets the requirements of the U.S. Pharmacopeia (USP) XXIII Class VI-50 and are compatible with blood and demonstrate no cytotoxic, mutagenic or irritant potential.

InterVascular considers that this device is substantially equivalent in intended use, composition and function to the predicate device, Meadox Graft Sizer manufactured by Meadox Medical Inc. The Meadox Graft Sizer received premarket clearance on May 7, 1986 under 510(k) K854431.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2002

InterVascular
c/o Ms. Amy Aulwes
Director, Regulatory Affairs
Health Policy Associates, Inc.
20 Walnut Street, Suite 12
Wellesley, MA 02481

Re: K022242
Trade Name: InterVascular InterGard Knitted Vascular Graft Sizer
Regulation Number: 21 CFR 870.3460
Regulation Name: Accessory to Vascular Graft Prosthesis
Regulatory Class: Class II (two)
Product Code: DSY
Dated: July 9, 2002
Received: July 11, 2002

Dear Ms. Aulwes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PRODUCT INDICATIONS FOR USE

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510(k) Number: K022242

Device Names: InterVascular InterGard Knitted Vascular Graft Sizer

Indications for Use: InterVascular InterGard Knitted Vascular Graft Sizer is an accessory to the InterGard Knitted Vascular Prosthesis and is designed to assist the physician in determining the size of the lumen of the host vessel in order to select the appropriate knitted vascular graft diameter.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ___

(Per 21 CFR 801.109)

for Bram Zuckerman

(Division Sign-Off) 8/14/02

Division of Cardiovascular and Respiratory Devices

510(k) Number K022242